



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94528d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

February 4, 2004

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 04-19

Dennis Lagler, Owner
Lagler Dairy
13207 NE 117th Ave.
Vancouver, Washington 98662-1281

WARNING LETTER

Dear Mr. Lagler:

An investigation at your dairy located at 13207 NE 117th Ave., Vancouver, WA, by our investigator on December 11-12, 2003, confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 342(a)(2)(C)(ii) and (a)(4). You also caused the adulteration of a new animal drug because you used the new animal drug in a manner that does not conform to its approved uses or the extralabel use regulations at Title 21, Code of Federal Regulations, Part 530 (21 CFR Part 530). This caused the drug to be unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b, and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act, 21 U.S.C. § 342(a)(2)(C)(ii), if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act, 21 U.S.C. § 360b. On or about October 10, 2003, you sold a culled dairy cow, back tag #891, identified on USDA-FSIS Lab Form #433947, for slaughter as human food to [REDACTED]. This cow previously bore ear tag #7310, was hauled by [REDACTED] and was subsequently identified with back tag #891 by the auction yard. [REDACTED] then sold the cow to [REDACTED]. USDA analysis of a tissue sample from the cow with back tag #891 identified the presence of penicillin at 0.14 parts per million (ppm) in the kidney. The tolerance for penicillin in edible tissue is 0.05 PPM. 21 CFR 556.510.

A food is adulterated under Section 402(a)(4) of the Act, 21 U.S.C. § 342(a)(4), "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so

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inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following conditions on your farm:

1. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.
2. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

The investigation also determined that you adulterated a new animal drug within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5), when you failed to use the drug in conformance with its approved conditions of use or the extralabel use regulations at 21 CFR Part 530. Specifically, you use the drug penicillin in excess of the labeled dosage without a prescription for such use. Extralabel drug use is permitted only on the lawful order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and in conformance with all other criteria set forth in 21 CFR Part 530, including that there may be no residue above established tolerance levels. Your use of penicillin failed to comply with the extralabel use regulations, causing the drug to be unsafe under Section 512(a) of the Act, 21 U.S.C. § 360b, and adulterated within the meaning of Section 501(a)(5) of the Act, 21 U.S.C. § 351(a)(5).

We request that you take prompt action to ensure that dairy cows and calves that you offer for sale as human food will not be adulterated with drugs or contain illegal residues. Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act, 21 U.S.C. § 331(a). Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act, 21 U.S.C. § 331(k).

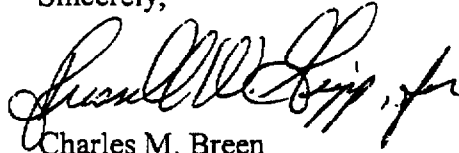
You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Please respond in writing within fifteen (15) working days of the receipt of this letter of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed.

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Please send your reply to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have questions regarding any issue in this letter, please contact Mr. Williamson at (425) 483-4976.

Sincerely,



Charles M. Breen
District Director

cc:



cc w/copy of FDA-483:

Dr. Murli M. Prasad
Food Safety & Inspection Service
Western Regional Office
620 Central Avenue, Building 2C
Alameda, California 94501